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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/748,127	12/27/2000	Chunhua Yan	CL000685	4150

25748 7590 08/26/2002

CELERA GENOMICS CORP.
ATTN: WAYNE MONTGOMERY, VICE PRES, INTEL PROPERTY
45 WEST GUDE DRIVE
C2-4#20
ROCKVILLE, MD 20850

EXAMINER
FRONDA, CHRISTIAN L

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 08/26/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/748,127	Boyds et al.
Examiner	**Art Unit**
Christian L. Fronda	1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Mar 11, 2002*.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *4-6, 8-11, 13, and 22-29* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *4-6, 8-11, 13, and 22-29* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☒ The proposed drawing correction filed on *May 8, 2001* is: a) ☒ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Applicants' election of Group III, claims 4-6, 8-11, and 22-23, in Paper No. 11 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Applicants'request to examine claim 13 and new claims 24-29 in Paper No. 11 is acknowledged. Claim 13 and new claims 24-29 will be examined with the elected invention of Group III.

Applicants' request in Paper No. 11 to cancel claims 1-3, 5-7, 10-12, and 14-23 which are directed toward non-elected subject matter is acknowledged. The restriction requirement is still deemed proper for reasons of record and is therefore made FINAL.

2. Claims 4-6, 8-11, 13, and 22-29 are under consideration in this Office Action.

Priority

3. Applicant's claim for domestic priority under 35 U.S.C. 119(e) for US provisional application 60/212,840 is acknowledged.

Nucleotide Sequence and/or Amino Acid Sequence Disclosures

4. The requirements stated on the "NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES" attached to the Office Action dated 06/03/2002 (Paper No. 13) have been withdrawn. A paper copy of the Sequence Listing has been entered and matched with the application file.

Drawings

5. The proposed drawing corrections filed on 5/8/2001 (Paper No. 4) have been approved and entered. A proper drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The correction to the drawings will not be held in abeyance.

The United States Patent and Trademark Office no longer makes drawing changes. See 1017 O.G. 4. It is applicant's responsibility to ensure that the drawings are corrected. Corrections must be made in accordance with the instructions below.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. **Correction of Informalities -- 37 CFR 1.85**
New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statu-tory period set for reply in the "Notice of Allowability." Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. **Corrections other than Informalities Noted by Draftsperson on form PTO-948.**
All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections
Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.185(a). Failure to take corrective action within the set (or extended) period will result in **ABANDONMENT** of the application.

Specification

6. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The following title is suggested: Isolated nucleic acid molecule encoding cytochrome p450.

Claim Rejections - 35 U.S.C. § 101

7. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claims 4-6, 8-11, 13, and 22-29 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Applicant discloses the nucleotide sequences of SEQ ID NOs: 1 and 3 and the deduced amino acid sequence of SEQ ID NO: 2. Applicants state that based on homology searches that the protein consisting of SEQ ID NO: 2 is a protein related to the cytochrome p450 drug-metabolizing enzyme subfamily which is a generic asserted utility. The specification does not specifically disclose the function/activity of the protein consisting of SEQ ID NO: 2 or its relationship to any disease. The specification does not show any enzyme assays that demonstrate that the protein consisting of SEQ ID NO: 2 has cytochrome p450 activity. There is no disclosed or "real world" utility associated with the nucleic acid of SEQ ID NO: 1, the nucleic acid of SEQ ID: 3, or the protein of SEQ ID NO: 2. It appears that the main utility of the nucleic acids and protein is to carry out further research to identify the biological function and possible diseases associated with the nucleic acids and protein. Substantial utility defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utility. Thus, the claimed invention has no specific and substantial asserted utility or a well established utility.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 4-6, 8-11, 13, and 22-29 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above in the rejection of the

claims under 35 U.S.C. § 101, one skilled in the art clearly would not know how to use the claimed invention.

11. Claim 13 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether undue experimentation is required, are summarized In re Wands [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of the claim encompasses any method for detecting the presence of a nucleic acid molecule in a sample by hybridizing any oligonucleotide probe comprising any 20 contiguous nucleotides that will hybridize to a nucleic acid molecule that encodes a protein comprising the amino acid sequence of SEQ ID NO: 2, the nucleotide sequence of SEQ ID NO: 1, or the nucleotide sequence of SEQ ID NO: 3.

The state of the prior art as exemplified by Wallace et al. and Sambrook et al. is such that determining the specificity of hybridization probes is empirical by nature and the effect of mismatches within an oligonucleotide probe is unpredictable. Even if the probe is a 20mer, the total number of hits in a database search is 143,797,728 which suggests that some of the probes encompassed by the claims would not preferentially hybridize to a nucleic acid molecule that encodes a protein comprising the amino acid sequence of SEQ ID NO: 2, the nucleotide sequence of SEQ ID NO: 1, or the nucleotide sequence of SEQ ID NO: 3. Therefore, predictability of which 20mer oligonucleotide probe will hybridize specifically and preferentially to a nucleic acid molecule that encodes a protein comprising the amino acid sequence of SEQ ID NO: 2, the nucleotide sequence of SEQ ID NO: 1, or the nucleotide sequence of SEQ ID NO: 3 is extremly low.

The specification does not provide guidance with respect to the specific nucleotide sequence of any oligonuleotide probe comprising at least 20 contiguous nucleotides that will specifically and preferentially hybridize to a nucleic acid molecule that encodes a protein comprising the amino acid sequence of SEQ ID NO: 2, the nucleotide sequence of SEQ ID NO: 1, or the nucleotide sequence of SEQ ID NO: 3. The amount of experimentation to determine the specific nucleotide sequence of any oligonuleotide probe comprising at least 20 contiguous nucleotides that will specifically and preferentially hybridize to a nucleic acid molecule that encodes a protein comprising the amino acid sequence of SEQ ID NO: 2, the nucleotide sequence of SEQ ID NO: 1, or the nucleotide sequence of SEQ ID NO: 3 is enormous. Such experimentation entails performing extensive hybridiztion experiments with every 20mer

oligonucleoitde probe possible to determine which 20mer oligonucleoitde probe will specifically and preferentially hybridize to a nucleic acid molecule that encodes a protein comprising the amino acid sequence of SEQ ID NO: 2, the nucleotide sequence of SEQ ID NO: 1, or the nucleotide sequence of SEQ ID NO: 3 in a nucleic acid sample.

The Examiner finds that one skilled in the art would require additional guidance, such as information regarding the specific nucleotide sequence of the oligonucleotide probe which will specifically and preferentially hybridize to a nucleic acid molecule that encodes a protein comprising the amino acid sequence of SEQ ID NO: 2, the nucleotide sequence of SEQ ID NO: 1, or the nucleotide sequence of SEQ ID NO: 3 in a nucleic acid sample. Without such a guidance, the experimentation left to those skilled in the art is undue.

12. Claims 4, 8, 9, 24, 27-29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention encompass any nucleotide sequence that encodes a protein comprising the amino acid sequence of SEQ ID NO: 2 or a full complement thereof. The specification, however, only provides the following representative species encompassed by these claims: (1) a nucleic acid molecule consisting of the nucleotide sequence of SEQ ID NO: 1, (2) a nucleic acid molecule consisting of the nucleotide sequence of SEQ ID NO: 3, and (3) a polypeptide consisting of the amino acid sequence of SEQ ID NO: 2. There is no disclosure of any particular structure to function/activity relationship in the disclosed species. The specification does not provide a written description of the nucleotide sequence that is 5' and 3' of any nucleotide sequence that encodes a protein comprising the amino acid sequence of SEQ ID NO: 2 or a full complement thereof. The specification does not provide a written description of the amino acid sequence that is N-terminal and C-terminal of SEQ ID NO: 2. The specification also fails to describe additional representative species of these nucleic acid molecules and polypeptides by any identifying structural characteristics or properties for which predictability of structure is apparent.

Given this lack of additional representative species as encompassed by the claims, Applicant has failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicant was in possession of the claimed invention. Claims 8, 9, 24, and 27-29 which depend from defective claim 4 are also rejected because they do not correct the defect of claim 4. Amending the claims to recite that the isolated nucleic acid molecule encodes a protein having cytochrome p450 activity may overcome this rejection.

Conclusion

13. No claims are allowed.

14. The reference made of record and not relied upon is considered pertinent to applicant's disclosure: Isogai et al. (GenBank Accession AK027605) teach a nucleotide sequence from human which is 81.5% identical to SEQ ID NO: 1.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (703)305-1252. The Examiner can be contacted Monday-Friday from 8:30AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703)308-3804. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703)308-0196.

Christian L. Fronda
Patent Examiner
Technology Center 1600
Art Unit 1652